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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,761	10/29/2003	Guixue Yu	HA0769 DIV	6656

23914 7590 01/07/2005

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EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,761	YU ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>12/23/04</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/1/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Priority

The priority to US 10/090288 has been acknowledged.

Claims pending 1-14, 16-19.

Claims 20-23 are withdrawn.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 16-19 in part, drawn to compounds and simple pharmaceutical compositions of formula I wherein E is as given in claim 9, W is azetidynyl or imidazolyl wherein azetidynyl or imidazolyl are optionally substituted with lower alkyl, G is A1-NR18COR19, A1-NR20CONR18R19, A1-NR18CO2R17, A1-NR18SO2R17, wherein A1 is a bond R13, R14, R15 and R16 are hydrogen, R1 and R2 do not form a ring, classified in class 546, 514, subclass 18, 184; 278, 315.
- II. Claims 1-14, 16-19 in part, drawn to other variables of G, W, E, R2 and other R's different from that given in group I, classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

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inventions have a different core with the numerous variables and permutations and combinations and hence different bonding and geometric configurations and arrangements.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Laurelee Duncan on 12/22/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-14, 16-19 in part, drawn to compounds and simple pharmaceutical compositions of formula I wherein E is as given in claim 9, W is azetidiny1 or imidazolyl wherein azetidiny1 or imidazolyl are optionally substituted with lower alkyl, G is A1-NR18COR19, A1-NR20CONR18R19, A1-NR18CO2R17, A1-NR18SO2R17, wherein A1 is a bond R13, R14, R15 and R16 are hydrogen, R1 and R2 do not form a ring. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-14, 16-23 in part are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Applicants can file a divisional on the cancelled non-elected subject matter without prejudice in due course.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 15 of U.S. Patent No. 6713487.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to a genus that is encompassed by the patent.

Claim Rejections - 35 USC § 103

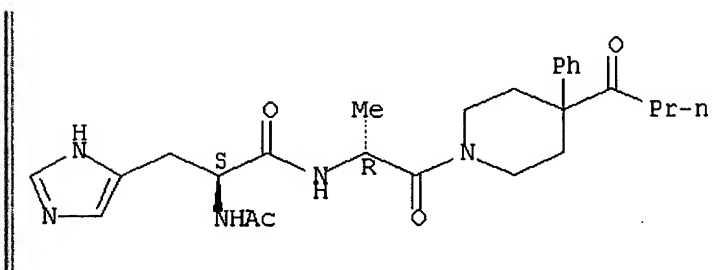
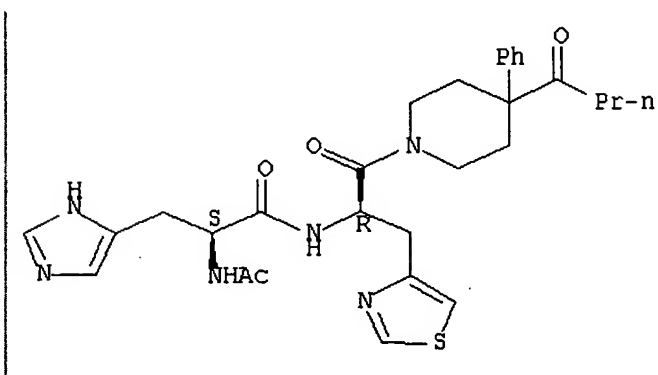
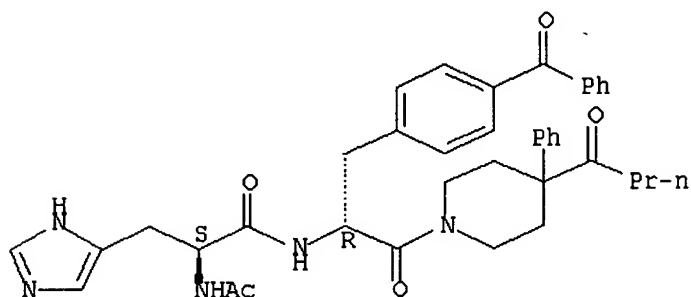
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-14, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5804578 Chakravarthy et al (also WO 97/36873 Chakravarthy et al).

Applicants elected group compounds are drawn to



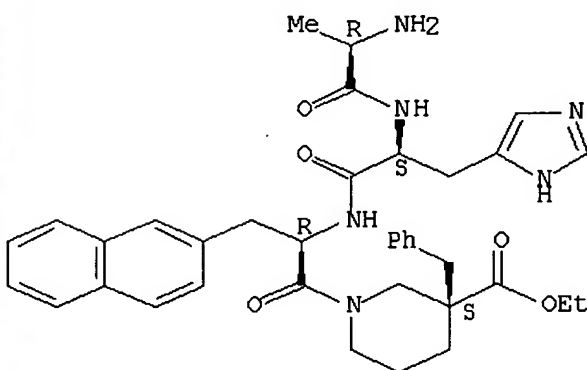
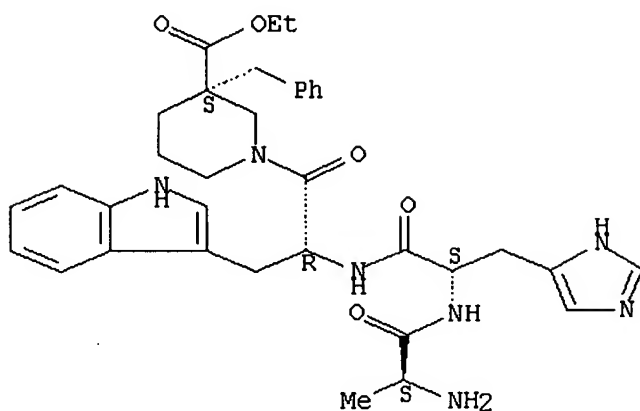
Determination of the scope and content of the prior art (MPEP §2141.01)

US 5804578 teaches

Compounds of the following structures

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PAGE 1-A



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The prior art has substituent on the meta position of the piperidine instead of the para position.

These compounds are also used as growth hormones.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Thus with a difference in the substituent location, without any showing of unexpected results with the compounds of the prior art one consider it a prima facie obvious to make positional modification to obtain the compounds of the invention.

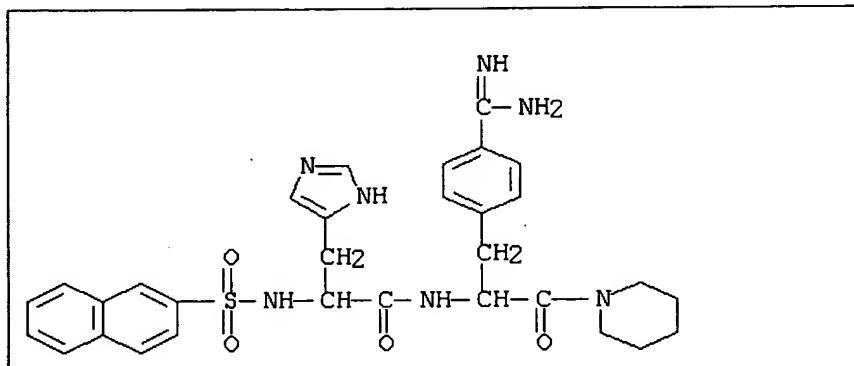
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Applicants are required to clearly show the unexpected results over the compounds of this prior art.

Prior Art Cited not relied upon:-

Journal of Enzyme Inhibition 2001 Vol 16 (3) pages 241-249 teaches similar compounds with the imidazole and the NHSO₂-aryl but the piperidine group is not the same as the elected

group as given in claim 9.



WO02/069905 is applicants own WO document with the priority to the same provisionals.

Conclusion

The claims are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
December 23, 2004

RDesai
12/23/04